1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

MITIL TABLETS

COMPOSITION

Each tablet of MITIL TABLETS contains 5 mg of prochlorperazine as a maleate salt.

Excipients:

Lactose, magnesium stearate, microcrystalline cellulose, powdered vegetable stearin, starch maize

Contains sugar: Lactose 63,7 mg

CATEGORY AND CLASS

A 2.6.1 Phenothiazines and their derivatives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Prochlorperazine, like its related molecules chlorpromazine and trifluoperazine, is a psychotherapeutic medicine believed to act at the subcortical level of the brain, principally it depresses the central nervous system.

Prochlorperazine is more potent than chlorpromazine but less so than trifluoperazine. The depressant action, hypotensive effect, antimuscarinic activity, potentiation of central nervous system depressants, and antihistaminic activity of prochlorperazine are all less than the respective effects of chlorpromazine.

INDICATIONS

MITIL TABLETS are used in the control of mild and moderate mental and emotional disturbances, characterised by anxiety, tension and agitation.

These tablets are used in the treatment of Meniere's syndrome, labyrinthitis, vertigo and migraine. It is also particularly effective for the prevention and treatment of nausea and vomiting.

CONTRAINDICATIONS

Contraindicated in patients with pre-existing central nervous system depression or coma, bone marrow suppression, or phaeochromocytoma. Central nervous system depression may be enhanced by other medicines with central nervous system-depressant properties including alcohol, general anaesthetics, hypnotics and sedatives, and opioid anaesthetics.

Phenothiazines effects on the vomiting centre may mask the symptoms of overdosage of other medicines, or of disorders such as gastrointestinal obstruction.

Should not be given to children weighing under 10 kg.

Safety in pregnancy and lactation has not yet been established therefore MITIL TABLETS are best avoided.

WARNINGS AND SPECIAL PRECAUTIONS

Usage of MITIL TABLETS may lead to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines.

Severe dystonic reactions have followed the use of MITIL TABLETS, particularly in children and adolescents. It should therefore be used with extreme care in children.

Geriatric, emaciated, or debilitated patients usually required a lower initial dose, the dosage being gradually increased as needed and tolerated.

Use with caution in patients with impaired liver, kidney, cardiovascular, cerebrovascular, and respiratory function and in those with closed-angle glaucoma, Parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis, or prostatic hypertrophy.

Care is required in epileptic patients receiving anticonvulsant therapy as phenothiazines may lower the seizure threshold.

Elderly and debilitated patients may be more prone to the adverse effects of MITIL TABLETS. Regular eye examinations and the monitoring of haematological parameters is advisable for patients receiving long term MITIL TABLETS therapy.

Mild symptoms resembling the withdrawal symptoms of dependence have been seen following the abrupt withdrawal of phenothiazines from patients receiving prolonged maintenance therapy.

Effects on ability to drive and use machines

Usage of MITIL TABLETS may lead to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines. Patients should be warned against operating vehicles or machinery, or performing potentially hazardous tasks.

Excipients

Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take MITIL TABLETS.

INTERACTIONS

Most common interactions encountered with phenothiazines are adverse effects resulting from concomitant administration of medicines with similar pharmacological action. When given with other hypotensives a severe hypotensive effect can be produced. Phenothiazines reduce the antihypertensive action of guanethidine and other adrenergic neurone blockers. May also potentiate the adverse effects of other antimuscarinics.

Concomitant administration of metoclopramide may increase the risk of neuroleptic-induced extrapyramidal effects, and antiarrhythmics which prolong the QT interval may increase the likelihood of ventricular arrhythmias.

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not yet been established therefore MITIL TABLETS are best avoided (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Tablets are not suitable for many paediatric patients' requirements and should not be given to children weighing less than 10 kg.

Geriatric, emaciated and debilitated patients usually required a lower initial dose, the dosage being gradually increased as needed and tolerated.

PREVENTION OF NAUSEA AND VOMITING:

5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS two or three times a day.

TREATMENT OF NAUSEA AND VOMITING:

20 mg (4 tablets) of MITIL TABLETS given orally; further doses may be given as required.

TREATMENT OF MIGRAINE:

20 mg (4 tablets) of MITIL TABLETS at once followed, if required, by 10 mg (2 tablets) of MITIL TABLETS two hours later. In an established attack if the patient is unable to retain tablets, treatment may be administered in a different form (25 mg of prochlorperazine maleate suppository).

TREATMENT OF VERTIGO AS WELL AS THAT ASSOCIATED WITH MÉNIÈRES DISEASE:

15 mg to 30 mg (3 to 6 tablets) of MITIL TABLETS in divided doses; after several weeks the dose may gradually be reduced to 5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS daily.

TREATMENT OF PSYCHOSES:

12,5 mg (2½ tablets) of MITIL TABLETS twice a day for seven days adjusted gradually to 75 mg to 100 mg (15 to 20 tablets) of MITIL TABLETS daily according to the response. Some patients may be maintained on doses of 25 mg to 50 mg (5 to 10 tablets) of MITIL TABLETS daily.

TREATMENT OF NON-PSYCHOTIC ANXIETY DISORDERS:

5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS up to 3 to 4 times daily.

SIDE EFFECTS

Dry mouth, constipation, difficulty with micturition, blurred vision, and mydriasis may occur. Tachycardia and electrocardiographic changes may also occur. Hypotension (usually postural) is common.

Other side effects include delirium, agitation and, rarely, catatonic-like states, insomnia, depression, miosis, EEG changes and convulsions, nasal congestion, minor abnormalities in liver function tests, inhibition of ejaculation, impotence, and priapism.

Hypersensitivity reactions include urticaria, exfoliative dermatitis, erythema multiforme, and contact sensitivity. A syndrome resembling systemic lupus erythematosus has been reported. Photosensitivity reactions, jaundice and deposition of pigment in the skin, or more frequently in the eyes, may occur.

Haematological disorders such as haemolytic anaemia, aplastic anaemia, thrombocytopenic purpura, a potentially fatal agranulocytosis (have occurred within 4 to 10 weeks of starting treatment) and mild leucopenia may occur.

Extrapyramidal dysfunction can result in the following disorders: acute dystonia, a

Parkinsonism-like syndrome, and akathisia; late effects include tardive dyskinesia and perioral tremor.

Endocrine and metabolic functions may be altered resulting in the following: amenorrhoea, galactorrhoea, gynaecomastia, weight gain, hyperglycaemia and altered glucose tolerance. Body temperature regulation is impaired and may result in both hypo- or hyperthermia depending on environment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Acute hypotension, and severe extrapyramidal reactions.

In severe overdosage the stomach should be emptied by aspiration and lavage. Emetics are generally of little value. Treatment should be symptomatic.

IDENTIFICATION

Plain white, biconvex tablets engraved with the Lennon logo.

PRESENTATION

25 or 250 tablets are packed in a white polypropylene container and sealed with a white linear low density polyethylene snap-on cap with a tamper-proof tear-off seal together with a white foam insert and a leaflet.

25 or 250 tablets are packed in a round amber polyvinylchloride container and sealed with a white linear low density polyethylene snap-on cap with a tamper-proof tear-off seal and a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

J/2.6/184

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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